



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,350	12/29/2000	Stephen M. Coutts	252312005706	1391
25226	7590	12/05/2005		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER HUYNH, PHUONG N	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,350

Applicant(s)

COUTTS ET AL.

Examiner

Phuong Huynh

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-25 and 28-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-25 and 28-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/05 has been entered.
2. Claims 22-25 and 28-68 are pending.
3. Applicant urges the examiner to reconsider the restriction for the reasons of record (page 12 of amendment filed 9/26/05). Upon reconsideration, the restriction requirement of claims 28, 36, 39-41, 44-45, and 47 have been rejoined with the elected group.
4. Claims 22-25 and 28-68 are being acted upon in this Office Action.
5. The inadvertent typographical error where the Action was listed as responsive to a communication filed February 16, 2004 instead of December 16, 2004 in the Final Office Action Summary mailed 3/24/05 as pointed out by applicant is acknowledged. It should have been listed as responsive to a communication filed December 16, 2004. Please accept my apology.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of any conjugate formed by at least two analog molecule of any "unidentified immunogen" associated with any

Art Unit: 1644

antibody mediated autoimmune disorder conjugated to a chemically defined valency platform as set forth in claim 45.

The specification discloses only conjugates comprising at least two immunogens associated with antibody mediated pathology from thyroiditis (thyroglobulin), stroke (cardiolipin), male infertility (α -sperm), myasthenia gravis (acetylcholine receptor), rheumatic fever (carbohydrate complex), allergen, Rh hemolytic disease (D immunogen) that lack T cell epitope and conjugated to polyethylene glycol (valency platform) through a diamino or triamino functional group that provides branched groups and attachment sites at the termini of the valency platform as shown on page 31 of the specification.

With the exception of the specific immunogen associated antibody mediated pathology for the claimed conjugate, there is insufficient written description about the structure associated with function of any and all compound unidentified immunogen associated with any antibody-mediated autoimmune disorder for the claimed conjugate. This is because the structure or the amino acid sequence of the immunogen is required to make the analog that lacks T cell epitope for the claimed conjugates.

The specification discloses only the specific conjugate comprising the specific identified immunogens lacking T cell epitope from the specific antibody mediated autoimmune disease conjugated to a chemically defined valency platform molecule, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species of compound to describe the genus of unidentified immunogen in the claimed conjugate. Thus, Applicant was not in possession of the claimed genus. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398; *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC2004).

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Art Unit: 1644

9. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The “*unidentified* immunogen” in claim 45 is ambiguous and indefinite. One of ordinary skilled in the art cannot appraise the metes and bounds of the claimed invention.

10. The filing date of the instant claims is deemed to be the filing date of parent application USSN 08/118,055 filed 9/8/1993. Priority application USSN 07/914,869 filed 7/15/02 does not provide a written support for the specific conjugate of inducing specific conjugate formable by the conjugation of at least two analog molecules of the immunogen selected from carbohydrates, lipids, oligosaccharides, polypeptides, peptides, proteins, glycoproteins or lipoproteins and chemically defined valency platform molecule comprises branching groups, provided by attachment sites located at termini of the valency platform molecule and the valency platform molecule is chemically defined in that the number of branching groups predetermines the number of attachment sites.
11. The rejection of claims 22-27, 29-35, 37-38, 42-43 and 46 under 35 U.S.C. 102(e) as being anticipated by US Pat No 6,060,056 (filed 9/8/1993; PTO 892) is hereby withdrawn in view of the continuation application 07/652,648 as claimed in the ‘056 patent does not support the claimed limitation of the specific conjugate of inducing specific conjugate formable by the conjugation of at least two analog molecules of the immunogen selected from carbohydrates, lipids, liposaccharides, polypeptides, peptides, proteins, glycoproteins or lipoproteins and chemically defined valency platform molecule comprises branching groups, provided by attachment sites located at termini of the valency platform molecule and the valency platform molecule is chemically defined in that the number of branching groups predetermines the number of attachment sites. Thus the ‘056 patent has the filing date of 9/8/1993, which has the same priority date as instant application.
12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103(a) that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 1644

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering Patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
14. Claims 22-25, and 28-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 5,268,454 (filed Feb 8, 1991; PTO 892) in view of US Pat 5,276,013 (filed July 15, 1992; PTO 892).

The '454 patent teaches a method of making a conjugate for inducing B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology in an individual such as human suffering from the pathology (see col. 3, line s 50-54, in particular). The reference conjugate comprises an analog of the immunogen such as protein, carbohydrate, lipid, lipoprotein, glycoprotein, lipopolysaccharide, external antigen such as biological drugs, allergens, idiopathic contrast media, or self-immunogen such as thyroglobulin associated with thyroiditis, carbiolipin associated with stroke, α -sperm associated with male infertility, acetylcholine receptor associated with myasthenia gravis, or carbohydrate complex associated with rheumatic fever that binds specifically to B cells to which the T cell-dependent immunogen binds (see col. 3, lines 55 bridging col. 4, lines 1-20, in particular) conjugated to a chemically defined valency platform molecule such as non-immunogenic polymer polyethylene glycol (see entire document, claims 1-11 of the '454 patent, col. 3, line 45-67, col. 5, lines 1-10, in particular). The reference analog conjugated to the carrier polymer via one or more crosslinking reagents or heterobifunctional crosslinker such as sulfosuccinimidyl(4-idoacetyl) amino benzoate and functional groups such as amino acid side-chain groups such as amino, carbonyl, sulfhydryl groups or ethylenediamine on the analog and carrier (see col. 5, lines 37, in particular). The reference conjugates is formulated in a pharmaceutically acceptable carrier such as saline for injection (see col. 5, lines 52-67, in particular). The reference conjugate is useful for inducing specific B cell anergy to a T cell-dependent immunogen (see col. 3, lines 34-40, col. 7, line 48, in

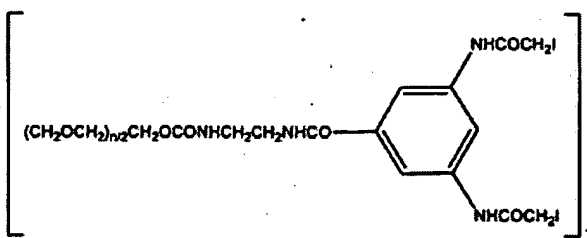
Art Unit: 1644

particular) or a method of treating an individual for an antibody-mediated pathology in which undesired antibodies are produced in response to a T cell-dependent immunogen such as thyroiditis, or stroke by administering a therapeutically effective amount of the composition comprising thyroglobulin conjugated to polyethylene glycol or cardiolipin conjugated to polyethylene glycol, respectively (see col. 4, lines 4-16, Disclosure of the Invention, in particular).

The invention in claim 22 differs from the teachings of the reference only in that the conjugate comprising at least two analog molecules instead of one analog molecule of the immunogen attached to a chemically defined valency platform molecule comprises branching groups that provided attachment sites located at termini of the valency platform molecule and the valency platform molecule is chemically defined in the number of branching groups predetermined the number of attachment sites instead of linear without branching groups.

The invention in claim 23 differs from the teachings of the reference only in that the conjugate wherein the branching groups are derived from a functional group diamino acid.

The invention in claim 68 differs from the teachings of the reference only in that the conjugate wherein the composition comprises a valency platform molecule of the formula:



wherein n is approximately 74.

The '013 patent teaches a method of making a chemically defined conjugates of biological stable valency platform molecule such as polyethylene glycol (see col. 4, lines conjugated to polynucleotides instead of analog of immunogen wherein the polynucleotides are attached to the amino and carboxyl termini of valency platform molecule via functional groups such as two diaminobenzoic acids (DABA) that has the same structure and formula as recited in instant claim 68 (see col. 17, lines 1-15, in particular). The '013 patent further teaches modification of the conjugates are obvious to those of skill in the conjugation chemistry (see col. 20, lines 29-32, in particular). The '013 patent further teaches the reference chemically defined conjugate are defined with respect to the site of attachment to the platform (see col. 3, lines 51-

54, in particular) and is useful as tolergens for treating SLE, which is antibodies mediated pathology anti-dsDNA (see col. 3, lines 58 bridging col. 4, lines 1-23, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the functional group in the conjugate comprising analog of the immunogen such as protein, carbohydrate, lipid, lipoprotein, glycoprotein, lipopolysaccharide, external antigen such as biological drugs, allergens, idiopathic contrast media, or self-immunogen that binds specifically to B cells to which the T cell-dependent immunogen binds conjugated to a chemically defined valency platform molecule such as polymer polyethylene glycol as taught by the '454 patent for the functional group such as diaminobenzoic acids (DABA) that provided attachment sites and branching located to the free ends of the valency platform molecule as taught by the '013 patent. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to do this because the '013 patent teaches modification of the conjugates is obvious to those of skill in the conjugation chemistry (see col. 20, lines 29-32, in particular) and the functional diamino group such as diaminobenzoic acids (DABA) provides attachment sites and branching located to the free ends of the valency platform which is useful for conjugating tolergens for treating antibodies mediated pathology (see col. 3, lines 58 bridging col. 4, lines 1-23, in particular).

The '454 patent teaches conjugate comprising an analog of the immunogen such as protein, carbohydrate, lipid, lipoprotein, glycoprotein, lipopolysaccharide, external antigen such as biological drugs, allergens, idiopathic contrast media, or self-immunogen such as thyroglobulin associated with thyroiditis, carbiolipin associated with stroke, α -sperm associated with male infertility, acetylcholine receptor associated with myasthenia gravis, or carbohydrate complex associated with rheumatic fever that binds specifically to B cells to which the T cell-dependent immunogen binds (see col. 3, lines 55 bridging col. 4, lines 1-20, in particular) and a chemically defined valency platform molecule such as non-immunogenic polymer polyethylene glycol is useful for inducing specific B cell anergy to a T cell-dependent immunogen (see col. 3, lines 34-40, col. 7, line 48, in particular) as a method of treating an individual for an antibody-mediated pathology in which undesired antibodies are produced in response to a T cell-dependent immunogen.

Art Unit: 1644

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 22-25, and 28-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,060,056. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claim 1 of the '056 patent recites a pharmaceutical composition comprising a therapeutic effective amount of the conjugate for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology comprising a non-immunogenic valency platform molecule and at least two analog molecules of the immunogen wherein (a) the analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and (b) the conjugate lacks T cell epitopes capable of activity T cells in said individual, and further wherein the analog molecules are selected from the group consisting of peptides, polypeptides, proteins, glycoproteins, lipoproteins, carbohydrates, lipids, and lipopolysaccharides (genus).

Pending claim 22 of instant application recites "A conjugate for inducing specific B cell anergy to a T cell dependent immunogen implicated in an antibody-mediated pathology in an individual suffering from the pathology, wherein said conjugate is formable by the conjugation of: (a) at least two analog molecules of the immunogen, wherein (1) said analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds

Art Unit: 1644

specifically, (2) the analog molecules lack T cell epitopes, and (3) the analog molecules are selected from the group consisting of carbohydrates, lipids, lipopolysaccharides, polypeptides, peptides, proteins, glycoproteins, and lipoproteins; and (b) a chemically defined valency platform molecule, wherein (1) the chemically defined valency platform molecule comprises branching groups; (2) the valency of the platform molecule is provided by attachment sites located at termini of the valency platform molecule and (3) the valency platform molecule is chemically determined in that the number of branching groups pre-determines the number of attachment sites (species).

Although the chemically defined platform molecule in claim 1 of the issued patent does not recite the branching groups, and does not have attachment sites at the termini of platform molecule of instant claims, the chemically defined platform molecule in the conjugate in claims of the '056 patent includes the linear (unbranched groups such as D-lysine) as well as the branching groups at the termini (genus). This is because the '056 patent teaches the valency platform molecule having a polyethylene glycol moiety such as PEG3350 having the formula $\text{CH}_2-(\text{CHOCH}_2)_n\text{CH}_2-$ wherein n is approx 74, which is (between 0 to 300) having a functional group such as the diamino benzoic acid or diamino acid of instant claim 23 located at the termini of the chemically defined platform molecule (see col. 13 through col. 15 of the '056 patent, claims 12-13 of the '056 patent, in particular). The analog molecules in the conjugate in claim 1 of the '056 patent includes at least two analog molecules that lack T cell epitopes and selected from peptides, polypeptides, proteins, glycoproteins, lipoproteins, carbohydrates, lipids, and lipopolysaccharides, an external immunogen, an external immunogen such as drug, allergen, D immunogen associated with Rh hemolytic disease, a self immunogen, a self immunogen that is associated with thyroiditis, diabetes, stroke, male infertility, myasthenia gravis, or rheumatic fever (see claims 1-5 of the '056 patent). The analog molecules in the conjugate of the '056 patent are the same (see claim 6 of '056 patent) or different (see claim 8 of the '056 patent) or unidentified (see claim 19 of the '056 patent, in particular). The conjugate of the '056 patent has four peptides which includes the four analog molecule of instant claim 25 (see col. 20, line 41, conjugate 5). The '056 patent teaches a pharmaceutical composition comprising the conjugate mentioned above and a pharmaceutically acceptable carrier (see claim 15 of the '056 patent, in particular) and suitable for injection (see col. 6, lines 33-34 of the '056 patent, in particular). The conjugate of the '056 patent wherein the valency platform molecule comprises a triethylene glycol moiety (see claim 13 of the '056 patent, in particular). The antibody mediated pathology

in the conjugate of the '056 patent is stroke where the immunogen in the conjugate is cardiolipin (see col. 4, line 57, in particular). Claim 16 of the '056 patent recites a method of inducing specific B cell anergy to a T cell-dependent, which includes the claimed method of inducing of inducing specific B cell anergy to a T cell-dependent in instant claim 48. Claim 17 of the '056 patent recites a method of treating an individual for an antibody-mediated pathology in which undesired antibodies are produced in response to a T cell-dependent immunogen comprising administering a therapeutically effective amount of the composition comprising a therapeutically effective amount of the conjugate comprising a nonimmunogenic valency platform molecule and at least two analog molecules of the immunogen wherein (a) the analog molecules bind specifically to surface antibody on B cells to which the T cell-dependent immunogen binds specifically and (b) the conjugate lacks T cell epitopes capable of activating T cells in the individual, the said method of the '056 patent includes the method of instant claim 49. Claim 39 of the issued patent recites a method of making conjugate comprising forming the conjugates by covalently bonding the analog molecules to the valency platform molecule, which include the method of making conjugate recited in instant claim 50. Likewise, the method recites in claim 18 of the '056 patent includes the method of making the composition recites in instant claim 51. The '056 patent further teaches the valency platform molecule comprises a polyethylene glycol moiety having a molecular weight of about 200 to about 8,000 (see col. 5, lines 62, in particular). The '056 patent also teaches that the analog molecules are attached to valency platform molecule via linker groups such as sulfosuccinimidy-(4-iodoacetyl) aminobenzoate (see col. 6, lines 21-27, in particular). Claim 15 of the '056 patent also recites a pharmaceutical composition comprising the conjugate mentioned above and a pharmaceutical acceptable carrier which includes the pharmaceutical composition recited in instant claims 65-67. The issuance of a patent to instant application (species) would anticipate the claims of the '056 patent (genus).

Applicants' arguments filed 9/26/05 have been fully considered but are not found persuasive.

Applicants' position is that the chemically defined platform molecule of instant claims reciting branch groups and attachment sites at particular locations is not "the same as" as polymer of D-lysine, which does not have branching groups in the same manner as the instant claims and does not have attachment sites at particular locations or the homogenous molecular weight as recited. Further, the newly amended claims are also not the same as a claim reciting D-lysine" because the valency platform molecule of the present claims recites attachment sites at termini of

the valency platform molecule and a valency that is predetermined by the number of branching groups.

In response, although claim 1 of the '056 patent does not recite the branching groups, and does not have attachment sites at the termini of platform molecule of instant claims, the chemically defined platform molecule in the conjugate in claims of the '056 patent includes the linear (unbranched group such as D-lysine) as well as the branching groups at the termini (genus). This is because the '056 patent teaches the valency platform molecule having a polyethylene glycol moiety such as PEG3350 having the formula $\text{CH}_2\text{-(CHOCH}_2\text{)}_n\text{CH}_2\text{-}$ wherein n is approx 74, which is (between 0 to 300) having a functional group such as the diamino benzoic acid or diamino acid of instant claim 23 located at the termini of the chemically defined platform molecule (see col. 13 through col. 15 of the '056 patent, claims 12-13 of the '056 patent, in particular). The analog molecules in the conjugate in claim 1 of the '056 patent includes at least two analog molecules that lack T cell epitopes and selected from peptides, polypeptides, proteins, glycoproteins, lipoproteins, carbohydrates, lipids, and lipopolysaccharides, an external immunogen, an external immunogen such as drug, allergen, D immunogen associated with Rh hemolytic disease, a self immunogen, a self immunogen that is associated with thyroiditis, diabetes, stroke, male infertility, myasthenia gravis, or rheumatic fever (see claims 1-5 of the '056 patent). The analog molecules in the conjugate of the '056 patent are the same (see claim 6 of '056 patent) or different (see claim 8 of the '056 patent) or unidentified (see claim 19 of the '056 patent, in particular).

17. Claims 22-25, and 28-68 are directed to an invention not patentably distinct from claims 1-39 of commonly assigned U.S. Patent No. 6,060,056 specifically for the same reasons stated in the obviousness-type double patenting mentioned above.
18. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,060,056, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the

Art Unit: 1644

conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.


19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
20. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

November 25, 2005


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600